

**MICHAEL S. KORCZYNSKI, PH.D.**  
**MIKKOR Enterprises, Inc.**  
**P.O. Box 573**  
**Lake Bluff, Illinois 60044-1219**

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- ISO** AAMI appointed U.S. Delegate (1990-present) to the International Standards Organization (ISO) Technical Committee 198 related to the development of worldwide sterilization standards. ISO and AAMI appointed Chairman of the U.S. Sub-Technical Advisory Group for ISO TC 198 Working Group 9 related to the development of aseptic processing standards. ISO appointed convenor of ISO TC 198 WG 9 that is responsible for developing a worldwide aseptic processing standard.
- U.S.P.** U.S.P. appointed member of Advisory Panel to the U.S.P. Microbiology Subcommittee. Moderator/Co-chair of technical sessions pertaining to sterilization, biological indicators, and preservative testing and aseptic processing at U.S.P. open conferences. Elected member of the USP Microbiology Subcommittee for Revision for the years 1995-2000. Elected to Microbiology Expert Council for 2000-2005.
- AAMI** Formerly the primary corporate voting representative for Abbott Laboratories to AAMI, (Association for the Advancement of Medical Instrumentation). Actively participated on several subcommittees that generated standards and guidelines; Biological Indicators Subcommittee, Industrial Stream Sterilization Working Group and Industrial Ethylene Oxide Sterilization Working Group.
- HIMA** During the 1970's, chaired and participated on HIMA's (Health Industry Manufacturers Association) Sterilization Committee that developed a series of sterilization related guidelines for the industry.

#### **EDUCATION**

1968-1969	Post-doctoral research fellow, Department of Microbiology, Duke University Medical Center	Biochemistry/Microbiology
1965-1968	Ph.D., Syracuse University	Microbiology
1962-1965	M.S., Rutgers University	Biological Sciences
1955-1959	B.A., University of Connecticut	Zoology

#### **AWARDS AND HONORS**

- National Institute of Health Traineeship, Syracuse University
- Recipient of National Cancer Institute Post-doctoral grant (declined)
- Recipient-nominee for Researcher of the Year Award, Abbott Laboratories, 1989
- Recipient-Researcher of the Year Award, Abbott Laboratories, 1994
- Recipient of a PDA award that established an annual "Korczynski" lecture grant to an international pharmaceutical scientist.

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## CAREER EXPERIENCE

2000 -

**Principal Consultant**  
MIKKOR Enterprises, Inc.  
Lake Bluff, Illinois and Bolivia, NC

Established a new incorporated enterprise for the specific purposes of:

- consulting for pharmaceutical projects related to product and/or process development with emphasis on sterilization technologies,
- and development of process technologies or laboratory equipment
- formed allied venture with Afton Scientific Corporation to provide technical guidance and clinical phase aseptic filling capabilities for start-up companies

1997 -1999

**Vice-President of Education/Director of PDA - Training & Research Institute**  
Associated with the PDA (Parenteral Drug Association)  
Baltimore County, Maryland

Responsible for the planning, development, and execution of the educational and training component of the PDA that provides pharmaceutical and biopharmaceutical education and training services to its 9,000 members located in the U.S. and abroad. Responsible for the build-out, start-up, and initial development of the PDA Training and Research Institute that has a mission to become the unprecedented Institute for education, training, and applied research in applied pharmaceutical sciences.

1977-1997

**Director, Microbiology and Sterilization Services**  
Research & Development - Hospital Products Division  
Abbott Laboratories, Abbott Park, Illinois

Aided in establishing Abbott Laboratories' expertise in the field of sterilization technology. Actively participated in obtaining NDA approvals for several major parenteral solutions and container/closure systems through technical interaction with the FDA, and participation during plant start-up inspections. Organized and directed a sterilization technology and microbiology area comprised of approximately 25 professional level development engineers and microbiologists. Developed a materials biocompatibility and hemocompatibility testing function within the area. Provided technical consultation to Corporate Quality Assurance, International, and other divisions. Interacted and communicated with Regulatory Affairs, Manufacturing Operations, Quality Assurance, Process Engineering, and R&D functions related to sterilization technology and IND/NDA related issues, and product development projects.

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1973-1977

**Manager, Sterilization Technology, Quality Assurance, Technical Services**  
Hospital Products Division, Abbott Laboratories, North Chicago, Illinois

Established a sterilization technology function within the division. Managed and provided technical guidance to sterilization technology, environmental control, and particulate technology areas within a QA Technical Services function. Developed major sterilization assurance and R&D related programs and policies. Technically interacted with the FDA during plant inspections and in support of new drug applications. Managed a staff of 55 people.

1969-1973

**Chief, Biological Laboratories Branch, Corporate Quality Assurance**  
Becton Dickinson & Company  
Research Triangle Park, North Carolina

Participated in the development of a Corporate Quality Assurance microbiological and product evaluation service group. Developed a microbiological quality control program and staffed a laboratory at a major cosmetic and drug contract packaging firm. Conducted activities and interacted with the EPA resulting in the registration of a disinfectant spray. Participated in Corporate Quality Assurance audits. Managed a staff of approximately 15 people.

1961-1965

**Sterilization Supervisor**  
Becton Dickinson & Company  
East Rutherford, New Jersey

Aided in the establishment of an ethylene oxide sterilization facility, and established a sterility testing laboratory for plastic disposable devices. Member of a corporate biological safety committee responsible for establishing biological and quality assurance policies as related to practical manufacturing activities. Supervised a staff of approximately eight people.

## **OTHER RELATED EXPERIENCE**


Author or co-author of over thirty publications and/or presentations.

Chairman, Co-chairman, and active participant on various technical and administrative committees of health care association such as HIMA, PMA, AAMI, and PDA.

PDA

President (1990-1991), Vice-President (1988-1989), Board of Directors, 2<sup>nd</sup> Vice President (1981), Past Chairman of the Research Committee, Publications Committee, and National Program Committee Chairman.

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#### PROFESSIONAL AFFILIATIONS

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American Society of Microbiology  
Society for Industrial Microbiology  
Parenteral Drug Association  
International Society for Pharmaceutical Engineering  
Drug Information Association

#### CIVIC ACTIVITIES

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- Past member, Environmental Advisory Committee to Lake County Board of Health,  
Lake County, Illinois
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